IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

OAK HILL HOMETOWN PHARMACY,

Petitioner,

CASE NO. 2:19-cv-00716

v.

UTTAM DHILLON, in his official capacity as Acting Administrator; and UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,

Respondents.

PETITIONER'S POST-HEARING BRIEF

Based on the materials submitted with its Petition for Injunction to Dissolve Immediate Suspension Order and Motion for Temporary Restraining Order, together with the evidence and argument presented to the Court on October 23 and 24, Oak Hill Hometown Pharmacy Inc. ("OHHP") is entitled to a Temporary Restraining Order and Preliminary Injunction dissolving the Administrator's *ex parte* suspension of its DEA Registration.

Standard and Scope of Review

These proceedings have prompted much discussion as to the proper scope and standard of review. The Administrator contends that this Court's review is limited to the evidence that was before him at the time of the ISO, yet the Administrator has been unable to determine what exactly that record includes. At a minimum, it seems that the record includes (1) the ISO; (2) the PDMP data; and (3) a government expert's report (which has never been disclosed). During the hearing, the Court indicated that the record would also likely include at least (4) materials which are referenced in the ISO, and (5) evidence contained in statements made by OHHP employees to

DEA agents during the course of its investigation — after the Administrator relied on both categories of materials in making his arguments to the Court.

Although consideration of those materials is appropriate, the Court is not required to confine its review thereto. "[W]hen faced with an inadequate administrative record, the 'record may be supplemented to provide, for example, background information or evidence of whether all relevant factors were examined by an agency,' but 'the new material should be merely explanatory of the original record and should contain no new rationalizations.'" *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145, 155 (D.D.C. 2012); *see also IMS, P.C. v. Alvarez*, 129 F.3d 618, 624 (D.C. Cir. 1997) (concluding that "where the agency fail[s] to examine all relevant factors or to adequately explain its grounds for decision," courts may consider supplemental information "outside the agency record"); *AT&T Infor. Sys., Inc. v. Gen. Servs. Admin.*, 810 F.2d 1233 (D.C. Cir. 1987) (explaining that "the record may be supplemented to provide, for example, background information or evidence of whether all relevant factors were examined by an agency"). Thus, this Court may consider evidence about factors that existed before the time of the agency's decision in this case and whether those factors were considered by the agency.

The United States Supreme Court similarly explained that where "there was such failure to explain administrative action as to frustrate effective judicial review," a court may obtain "additional explanation." *Camp v. Pitts*, 411 U.S. 138, 143-44 (1973). The Supreme Court went on to explain that *de novo* review is appropriate where an agency's decision is based on "inadequate factfinding procedures." *Id.* at 141-42 (citing *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402 (1971)).

Petitioner's proposed Exhibit 1, together with the live and proffered witness testimony, is offered as "background information or evidence of whether all relevant factors were examined by

an agency." *Holiday CVS, L.L.C.*, 839 F. Supp. 2d at 155. It contains no new rationalizations, and merely demonstrates that the Administrator "failed to examine all relevant factors." *See IMS, P.C.*, 129 F.3d at 624. Namely, the Administrator appears to have failed to consider at least:

- The West Virginia Board of Pharmacy's views regarding the legitimacy of out-of-State Subutex prescriptions (Tabs 3-5);
- The West Virginia DHHR's views regarding the availability of MAT treatment in the State of West Virginia (Tab 6);
- ASAM's National Practice Guideline for MAT (Tab 7);
- The FDA's views regarding the propriety of Subutex for the treatment of Opioid Use Disorder (Tabs 8-12);
- OHHP's actual practice with respect to the treatment of patients presenting with out-of-State Subutex prescriptions (Tabs 13-19, 22-25); and
- The explanations provided by OHHP employees to DEA agents — prior to the issuance of the ISO — about why the patients whose out-of-State Subutex prescriptions OHHP filled did not present unresolved red flags of diversion.

In sum, because the Administrator wholly failed to consider important aspects of the problem at issue, the scope of review is not limited to the three documents identified by the Administrator. Similarly, given the inadequacy of the Administrator's factfinding process, the standard of review applied by this Court need not be overly deferential.

Argument

I. OHHP is likely to succeed on the merits.

During the hearing on this matter, the Administrator took the position that the record was limited to what was before him at the time but could not inform the Court or the Petitioner as to what that actually included. The Administrator announced, and then meekly retreated from, his claim that Subutex can only be prescribed to pregnant women or patients with documented allergies. After two full half-days of evidence and argument, it is still not clear (1) what the

Administrator believes constitutes the record, (2) whether the Administrator stands by its initial position regarding the propriety of issuing Subutex prescriptions for the treatment of Opioid Use Disorder, or (3) what specific factual findings support the Administrator's finding that OHHP presents an "imminent danger to the public health or safety." *See* 21 U.S.C. § 824(d)(1).

What is clear is that the Administrator's inadequate process has frustrated the judicial review of his decision. It is also clear that the factual allegations underlying the Administrator's decision are largely false. It is clear that the Administrator ignored important aspects of the opioid epidemic that West Virginia is experiencing. And it is clear that the only actual finding made by the Administrator as required by 21 C.F.R. 1301.36(e) is, in the Administrator's words, a "typo."

Moreover, after the conclusion of the hearing, Petitioner uncovered additional false statements on which the Administrator apparently relied in obtaining his August 6, 2019 warrant. *See* ECF No. 3, *In Re: Oak Hill Hometown Pharmacy*, No. 5:19-MJ-30 (S.D.W. Va.). In that miscellaneous proceeding, the DEA's lead Diversion Investigator ("DI") LeeAnn Koziol describes a far broader record of information than has been previously disclosed by the Administrator. *See id.* at ¶¶3, 6, 8 (describing additional materials available to and reviewed by the Administrator). Most egregiously, DI Koziol therein falsely claims that:

> OAK HILL HOMETOWN PHARMACY has reduced the number of such prescriptions it fills following the DEA's inspection, but has continued to fill buprenorphine prescriptions written by doctors located outside of the state of West Virginia since November 28, 2018. That the majority of the prescriptions emanating from outside of the state of West Virginia were written by physicians located in Pennsylvania, which is a substantial distance from Oak Hill, West Virginia. That from November 28, 2018 to present, 60% of buprenorphine prescriptions filled by OAK HILL HOMETOWN PHARMACY were written by doctors located out of state.

See id. at ¶ 6.

Those allegations, like others relied on by the Administrator, are demonstrably and unequivocally false. The truth, which the DEA knew at the time, is that from November 28, 2018 through July 31, 2019, OHHP filled a total of forty Subutex prescriptions written by out-of-State doctors[1] and a total of sixty-two prescriptions written by in-State providers. In other words, *60% of buprenorphine prescriptions filled by Oak Hill Hometown Pharmacy were written by doctors located in this State*. And when limited to new prescription*s* accepted after the AIW — that is, excluding patients who were permitted only to obtain the balance of their earlier prescriptions — the number climbs to a staggering sixty-two out of seventy-three, or *84% of buprenorphine prescriptions filled by OHHP were written by in-State providers.*

The Administrator has never offered any cogent response to these facts. Instead, the Administrator protests that anything other than total deference would lead to "warehouses full" of information which potentially become relevant and available to the Administrator. Yet when pressed, the Administrator could not find within those warehouses a single statute, rule, or guideline which prohibits Subutex from being prescribed to treat Opioid Use Disorder. By contrast, OHHP has not offered "warehouses full" of information. OHHP submitted a concise factual presentation demonstrating that Subutex has been approved by the FDA for the treatment of Opioid Use Disorder and was so approved before the Administrator issued the ISO. That factual presentation relied on the "Dear Pharmacist" letter, Pharmacy Information Pamphlet, and other materials which are similarly approved by the FDA and which demonstrate that Subutex is

[1] Those forty out-of-State Subutex prescriptions filled by OHHP after the November 28, 2018 include (1) the patients permitted to obtain the balance of their prescriptions after the AIW, (2) the prescriptions issued to N.R. and M.V. the day after the AIW, and (3) the prescriptions issued to J.J.2 during her pregnancy. They are described in more detail in ECF No. 4-1, at 12-14.

appropriate for maintenance therapy for the treatment of addiction. The Administrator, for his part, pointed to largely nothing and insisted that he is nevertheless entitled to great deference.

OHHP then presented evidence that the supposed "red flags" are not red flags at all, and that anyone with a baseline comprehension of the issues faced by our state would know that (1) there are not enough MAT providers available; (2) federal law caps the number of patients that can be treated by existing providers; (3) there are few or no providers in many of the rural parts of this State; (4) as a result, many patients travel to Pennsylvania to obtain MAT; (5) those out-of-State treatments are not covered by insurance; and (6) Subutex is a cheaper treatment and has been available in generic form for some time. OHHP staff explained to this Court, as they explained to the DEA before the ISO, that the Agency misunderstood the situation on the ground in rural West Virginia and that neither the distance, the medication, nor the private payment for partial fills was a red flag. Instead, those characteristics were created by legitimate but unfortunate circumstances surrounding the treatment of opioid-dependent patients. In short, they were not indications of illicit diversion at all.

This Court heard that there were simply not enough MAT providers in West Virginia and that there were many counties in the state — including those near Oak Hill — where there *was not a single* MAT provider in the entire county. The Court heard, as did the DEA, that in the areas with MAT providers, many were not accepting new patients and that wait times could be many months or years. The Court heard, like the DEA, that there is an abundance of MAT providers in Pennsylvania, that they are more affordable, require fewer in-office visits, and thereby enable patients to maintain employment and to function in society while also receiving treatment for addiction.

This Court heard that traveling along Route 19 to get to your pharmacy is not a red flag but is a product of West Virginia and its communities. The Court heard that, due to the stigma surrounding addiction, many pharmacies did not and do not stock buprenorphine in any form. In response, the Administrator echoed the hollow refrain that he is entitled to great deference. But in order to enjoy the benefit of deference, the Administrator must first show that he followed an adequate process, considered all important aspects of the issue, and that his conclusions have sufficient support in a record that this Court can review. Because the Administrator (1) cannot demonstrate that OHHP presents an "imminent danger to the public," (2) relied on factual allegations which are demonstrably false; (3) failed to make the findings required by 21 C.F.R. 1301.36(e); (4) failed to consider important aspects of the problem at hand; and (5) relied on an "expert" who contradicts the FDA, OHHP is likely to succeed on the merits.

II. OHHP will suffer irreparable harm in the absence of a TRO and Preliminary Injunction.

OHHP presented largely uncontroverted evidence concerning the irreparable harm that it will suffer without relief. The lack of a DEA Registration is a death sentence for a pharmacy. OHHP has already lost a substantial portion of the patient base that its proprietor has worked so hard to assemble. Continued losses during the months-long administrative revocation process will almost certainly destroy the business that Martin Njoku built from scratch. Without relief from this Court, OHHP will be nothing more than an innocent victim of the Administrative State, deprived even of the revenue that it needs in order to defend itself.[2]

[2] The government's only response to the "irreparable harm" is to point to a separate pharmacy owned by Martin Njoku. But OHHP is the petitioner, not Martin Njoku.

III. The balance of hardships weighs in favor of granting the TRO.

The third prong for a TRO — the balance of hardships — is met. The hardship to OHHP of being forever put out of business, far outweighs any hardship to the Administrator. The administrative proceedings seeking to revoke OHHP's registration will continue and will not be hindered by this Court's action. There, the DEA will have the opportunity to demonstrate that OHHP's Registration is inconsistent with the public interest, and OHHP will have a similar opportunity to rebut that effort. In essence, the DEA does not face a hardship if this Court enjoins and dissolves the immediate suspension. The balance of hardships weighs heavily in favor of dissolving the immediate suspension.

IV. The TRO is in the public interest.

West Virginia has a powerful public interest in ensuring the availability of Medication Assisted Treatment for its citizens suffering from addiction. The evidence before the Court demonstrates that there are not enough providers to meet the needs of our citizens, and that pharmacies and physicians are reluctant to treat addicts. This reluctance stems from the stigma of treating a marginalized population, and from the intimidation that our providers feel regarding the constant threat of unwarranted interference by the federal government. Without OHHP, communities deeply scarred by the opioid epidemic and in dire need of available treatment will be further deprived of a much-needed brick in the path to recovery. In a case like this, the public interest clearly and strongly supports the issuance of a TRO.

Conclusion

The Administrator has acknowledged in this Court that his agency was asleep at the wheel during the inception of our opioid crisis. In his haste to show some activity, the Administrator has now authorized his agency to drive recklessly through the lives of West

Virginians, punishing the small businesses and healthcare providers who would be part of the solution. In his wake, the Administrator leaves the citizens of this State with less access to Medication Assisted Treatment, and further intimidates the healthcare providers who would provide addiction treatment where it is most needed. He has effectively shuttered Oak Hill Hometown Pharmacy for following the directives of the FDA, the WV DHHR, the WV Board of Pharmacy, and the nationally recognized guidelines for the treatment of Opioid Use Disorder. He did so based on factual allegations which are just plain false, and without making any of the specific findings which his own regulations require. Under any standard of review, the Administrator's action cannot be sanctioned. Because it will suffer irreparable harm, OHHP is entitled to a Temporary Restraining Order and Preliminary Injunction dissolving the Administrator's Immediate Suspension Order pursuant to 21 U.S.C. § 824(d)(1).

Dated: October 25, 2019

Respectfully submitted,
Oak Hill Hometown Pharmacy Inc.,
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